REMARKS/ARGUMENTS

Claims 1-12 and 23 are currently pending. Claims 12-22 directed to a non-elected invention have been canceled. Claim 23 has been added.

Applicants affirm the election of the invention in claims 1-12. Claims 12-22 have been canceled but applicants reserve the right to pursue these claims in a divisional application.

Claims 1 and 3-5 have been objected to because parenthesis have been used in the claims. The Office action cites MPEP §608.01 for the position that parenthesis are proper only when referring to elements in a figure. Applicants respectfully submit that the use of parenthesis in claims is not limited to identifying the elements in a figure. Although the MPEP indicates that reference numbers should be enclosed in parenthesis, there is no indication that this is the only appropriate use of parenthesis. The presence of the parenthesis do not render the claims indefinite and, in fact, applicants submit that the parenthetical content increases the clarity of the claims. Therefore, applicants respectfully request that the objection to claims 1 and 3-5 be withdrawn.

Claims 1-11 stand rejected under 35 U.S.C. §102(b) as being anticipated by WO 99/12524 ('524). Applicants respectfully submit that the '524 reference fails to disclose or suggest the pharmaceutical dosage form set forth in the claims of the pending application. The '524 application broadly discloses modified release multiple-unit compositions containing a non-steroid anti-inflammatory drug substance (NSAID). Muscle relaxants such as cyclobenzaprine are among a laundry list of other drug substances, which may be included with the NSAID. The reference to the release profile of a composition in the '524 publication addresses the release of the NSAID and provides no indication as to the release profile obtained with a composition containing a skeletal muscle relaxant. The broad disclosure in the '524 publication that a muscle relaxant could be combined with the NSAID is insufficient to anticipate the claims of the present application. Claim 1 specifically indicates that the dosage form provides therapeutically effective plasma concentration of the skeletal muscle relaxant. Applicants submit that this functional portion of the claim is a limitation that must be given patentable weight and is more than just a statement of future intended use. Claim 1 has been amended to clarify that the dosage

form provides a therapeutically effective plasma concentration of the skeletal muscle relaxant when administered to a patient in need of treatment. Therefore, applicants respectfully submit that claim 1, and the claims dependent thereon, are novel and non-obvious over the '524 publication.

The Office action further indicates that the composition advanced by the '524 publication would inherently provide the pharmacokinetic properties set forth in claims 3 and 4. The Office action indicates that since the essential elements of the '524 composition are identical to the instant compositions, the compositions would have the same physiochemical properties. Applicants respectfully submit that the disclosure in the '524 publication is simply insufficient to reach a conclusion that the same properties would be obtained. The composition set forth in the claims of the present application and the compositions disclosed in the '524 publication are significantly different. The broad disclosure of similar components provides very little, if any, information as to how these components, when combined into a pharmaceutical dosage form, will respond in during *in vivo* or *in vitro* dissolution. Reliance on an inherent disclosure in a reference must be based on more than mere conjecture. "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy,* 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990)(emphasis in original) There is certainly nothing in the broad disclosure in the '524 to necessarily lead to the properties of the dosage forms claimed in claims 3 and 4. Accordingly, it is respectfully submitted that the cited reference fails to disclose or suggest the invention as set forth in claims 3 and 4 and it is respectfully requested that the rejection of these claims be withdrawn.

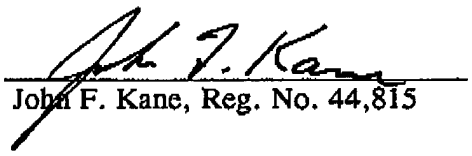
The claims have also been rejected as being anticipated or obvious over U.S. Patents 4,839,177 and 5,407,686. However, both of these references are directed to tablet cores and not multi-particulate pharmaceutical dosage forms as set forth in the claims of the present application. Claim 1 has been amended to clarify that the pharmaceutical dosage form is multi-particulate. However, applicants submit that claim 1 as originally presented also made clear that the pharmaceutical dosage form was multi-particulate and that it was directed to a composition

comprising a population of extended release beads. The disclosure in the cited references relating to coated core tablets provides no teaching that would be relevant to the multiparticulate dosage forms claimed in the present application. Furthermore, with respect to the '177 patent the uncated deposit-core does not act as an IR component and the coated deposit core is not a true sustained release component. Therefore, for at least these reasons, applicants submit that the claims of the pending application are novel and non-obvious over the cited references.

New claim 23 is directed to a more specific embodiment of the invention wherein the active-containing core particle comprises an inert core coated with an active-containing composition consisting essentially of a skeletal muscle relaxant. None of the cited references discloses or suggests such a dosage form.

In view of the foregoing, it is respectfully submitted that all of the pending claims are in condition for allowance and favorable action on the merits is requested. Any questions concerning this application may be directed to applicant's undersigned attorney at the telephone number indicated below.

Respectfully submitted,



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